Agency for Healthcare Research and Quality
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NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology.

Bibliographic Source(s)

Halperin JJ, Kurlan R, Schwalb JM, Cusimano MD, Gronseth G, Gloss D. Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2015 Dec 8;85(23):2063-71. [40 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

Recommendations

- Clinicians may choose to offer shunting as a treatment for patients with idiopathic normal pressure hydrocephalus (iNPH) in order to treat their subjective symptoms of iNPH and gait (Level C).
- Because there is a risk of significant adverse events (AEs), the risks and benefits of the procedure should be carefully weighed (Level B).
- Clinicians should inform patients with iNPH with elevated R_o that they have an increased chance of responding to shunting compared with those without such elevation (Level B).
- Clinicians may counsel patients with iNPH that an abnormal CSF infusion test (CSF-IT) or a positive response to repeated lumbar punctures (LPs) increases the chance of response to shunting (Level C).
- Clinicians may counsel patients with iNPH and their families that increasing age does not necessarily decrease the chance of a shunt being successful (Level C).
- Clinicians may counsel patients with suspected iNPH and with impaired cerebral blood flow (CBF) reactivity to acetazolamide, measured by single-photon emission computed tomography (SPECT), that they are possibly more likely to respond to shunting (Level C).

Definitions

Evidence Schemes for Classifying Articles

Therapeutic Scheme

Class I

- Randomized, controlled clinical trial (RCT) in a representative population
- Masked or objective outcome assessment
- Relevant baseline characteristics are presented and substantially equivalent between treatment groups, or there is appropriate statistical adjustment for differences
- Also required:
    a. Concealed allocation
    b. Primary outcome(s) clearly defined
    c. Exclusion/inclusion criteria clearly defined
    d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias
    e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required*:
        1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority
        2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose, and dosage adjustments are similar to those previously shown to be effective)
        3. The inclusion and exclusion criteria for patient selection and the outcomes of patients on the standard treatment are comparable to those of previous studies establishing efficacy of the standard treatment
        4. The interpretation of the study results is based on a per-protocol analysis that accounts for dropouts or crossovers

Class II

- Cohort study meeting criteria a–e above or an RCT that lacks one or two criteria b–e
- All relevant baseline characteristics are presented and substantially equivalent among treatment groups, or there is appropriate statistical adjustment for differences
- Masked or objective outcome assessment

Class III

- Controlled studies (including studies with external controls such as well-defined natural history controls)
- A description of major confounding differences between treatment groups that could affect outcome**
- Outcome assessment masked, objective, or performed by someone who is not a member of the treatment team

Class IV

- Did not include patients with the disease
- Did not include patients receiving different interventions
- Undefined or unaccepted interventions or outcome measures
- No measures of effectiveness or statistical precision presented or calculable

*Numbers 1–3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing, the class is automatically downgraded to Class III

**Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data)

Prognostic Scheme

Class I

A cohort study of a broad spectrum of persons at risk for developing the outcome (e.g., target disease, work status). The outcome is defined by

an acceptable reference standard for case definition. The outcome is objective or measured by an observer who is masked to the presence of the risk factor. Study results allow calculation of measures of prognostic accuracy.

Class II

A case-control study of a broad spectrum of persons with the condition compared to a broad spectrum of controls or a cohort study of a broad spectrum of persons at risk for the outcome (e.g., target disease, work status) where the data was collected retrospectively. The outcome is defined by an acceptable reference standard for case definition. The outcome is objective or measured by an observer who is masked to the presence of the risk factor. Study results allow calculation of measures of prognostic accuracy.

Class III

A case-control study or a cohort study where either the persons with the condition or the controls are of a narrow spectrum where the data was collected retrospectively. The outcome is defined by an acceptable reference standard for case definition. The outcome is objective or measured by an observer who did not determine the presence of the risk factor. Study results allow calculation of measures of a prognostic accuracy.

Class IV

Studies not meeting Class I, II, or III criteria, including consensus, expert opinion, or a case report.

Classification of Recommendations

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Idiopathic normal pressure hydrocephalus (iNPH)

Guideline Category

Counseling

Management

Treatment

Clinical Specialty

Neurological Surgery

Neurology

Intended Users

Physicians

Guideline Objective(s)

To evaluate evidence for utility of shunting in idiopathic normal pressure hydrocephalus (iNPH) and for predictors of shunting effectiveness

Target Population

Patients with idiopathic normal pressure hydrocephalus (iNPH)

Interventions and Practices Considered

1. Ventricular shunting
2. Consideration of risk of significant adverse effects (weighing risks vs. benefits)
3. Counseling and informing patients/families that:
    - Elevated R_o increases chance of responding to shunting compared with those without elevation
    - External lumbar drainage or to repeated lumbar punctures increases chance of response to shunting
    - Increasing age does not decrease the chance of successful shunting

Major Outcomes Considered

- Interview-Based Impression of Change, plus interview (CIBIC-Plus) assessment of global ratings
- Cognitive, balance, gait, and urinary functioning

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The panel performed an initial search of MEDLINE, EMBASE, LILACS, and the Cochrane Database from 1980 to September 2012, limited to English-language publications, using the search terms ("normal pressure hydrocephalus" or "NPH" or "adult hydrocephalus syndrome" or "hydrocephalus") and ("shunting" or "treatment") and ("trial" or "outcome" or "predictors" or "response") and "neurosurgery." The search identified 438 citations. The panel performed an updated search of MEDLINE and Cochrane from 2012 to November 2013 using ("normal pressure hydrocephalus" or "NPH") and filtering manually with terms of initial search. Subsequent to this update, 2 additional relevant studies were published and are included. The panel excluded case reports, editorials, meta-analyses, review articles, duplicative reports, and articles regarding only secondary normal pressure hydrocephalus (NPH), including fewer than 10 patients with idiopathic NPH (iNPH) or suspected iNPH (as smaller numbers would lack statistical power), using no comparison group, or following patients for response to therapy for less than 3 months. At least 2 reviewers working independently of each other screened each of the remaining abstracts for relevance. If discordant conclusions could not be resolved by consensus, the panel included a third reviewer. Two panelists reviewed in detail the articles considered relevant to either of the questions, using pre-established criteria for relevance.

Number of Source Documents

This selection process yielded a total of 36 articles. There were 3 Class I, 8 Class II, and 7 Class III studies relevant to the prognostic question. Three Class III studies were identified for the therapeutic question. All remaining articles had Class IV evidence.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Schemes for Classifying Articles

Therapeutic Scheme

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    e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required*:
        1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority
        2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose, and dosage adjustments are similar to those previously shown to be effective)
        3. The inclusion and exclusion criteria for patient selection and the outcomes of patients on the standard treatment are comparable to those of previous studies establishing efficacy of the standard treatment
        4. The interpretation of the study results is based on a per-protocol analysis that accounts for dropouts or crossovers

Class II

- Cohort study meeting criteria a–e above or an RCT that lacks one or two criteria b–e
- All relevant baseline characteristics are presented and substantially equivalent among treatment groups, or there is appropriate statistical adjustment for differences
- Masked or objective outcome assessment

Class III

- Controlled studies (including studies with external controls such as well-defined natural history controls)
- A description of major confounding differences between treatment groups that could affect outcome**
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Class IV

- Did not include patients with the disease
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*Numbers 1–3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing, the class is automatically downgraded to Class III

**Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data)

Prognostic Scheme

Class I

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Class II

A case-control study of a broad spectrum of persons with the condition compared to a broad spectrum of controls or a cohort study of a broad spectrum of persons at risk for the outcome (e.g., target disease, work status) where the data was collected retrospectively. The outcome is defined by an acceptable reference standard for case definition. The outcome is objective or measured by an observer who is masked to the presence of the risk factor. Study results allow calculation of measures of prognostic accuracy.

Class III

A case-control study or a cohort study where either the persons with the condition or the controls are of a narrow spectrum where the data was collected retrospectively. The outcome is defined by an acceptable reference standard for case definition. The outcome is objective or measured by an observer who did not determine the presence of the risk factor. Study results allow calculation of measures of a prognostic accuracy.

Class IV

Studies not meeting Class I, II, or III criteria, including consensus, expert opinion, or a case report.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Each article was classified according to the American Academy of Neurology's (AAN's) classification schemes for therapeutic (2011) and prognostic (2004) articles (see the "Rating Scheme for the Strength of the Evidence" field). Table e-1 in the data supplement (see the "Availability of Companion Documents" field) presents studies rated above Class IV (with one exception).

Many included studies lacked generalizability because patients, while representing a typical clinical spectrum, were preselected for surgery on the basis of tests other than the ones being studied. In these studies, the panel upgraded or downgraded certain therapeutic and prognostic conclusions using the formal AAN-modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology (see tables e-2 and e-3 in the data supplement [see the "Availability of Companion Documents" field]).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In November 2010, the American Academy of Neurology (AAN) Guideline Development, Dissemination, and Implementation Subcommittee formed a panel of experts to develop this guideline according to the processes outlined in the 2004 AAN process manual, with 2 exceptions: the 2011 AAN process manual was used in the approach to developing conclusions and the therapeutic classification of evidence scheme subsequently updated from the 2011 AAN process manual was used (see the "Availability of Companion Documents" field).

The panel systematically reviewed the literature regarding the diagnosis and treatment of idiopathic normal pressure hydrocephalus (iNPH). The panel asked 2 questions:

1. What is the efficacy of ventricular shunting for iNPH (therapeutic question)?
2. Are there reliable clinical or laboratory predictors of a successful outcome of shunting (prognostic question) (efficacy and successful outcome both defined as a persistent, objectively demonstrable, and clinically meaningful improvement after shunting)?

The panel linked recommendations directly to the evidence (see the "Rating Scheme for the Strength of the Recommendations" field).

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The American Association of Neurological Surgeons and the Congress of Neurological Surgeons affirm the educational content of this document.

Drafts of the guideline have been reviewed by at least 3 American Academy of Neurology (AAN) committees, a network of neurologists, *Neurology* peer reviewers, and representatives from related fields.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Shunting is possibly effective in patients with idiopathic normal pressure hydrocephalus (iNPH), with a 96% chance of subjective improvement, and a 83% chance improvement on the timed walk test at 6 months.

Potential Harms

Shunting is associated with potential morbidity and mortality. One review found a pooled mean shunt complication rate of 38% and an overall combined rate of permanent neurologic deficit and death of 6%. Another publication reported mortality rates between 5% and 15% for the shunting procedure. In the recently reported SINPHONI multicenter trial, 22% of shunted patients experienced significant adverse events (AEs). In addition to the costs of hospitalization and surgery, patients with implanted shunts are at risk of shunt failure, ventriculitis, and shunt infections. The prolonged lumbar drainage diagnostic procedure is associated with a risk of meningitis and death of 1.8%–3.6% and 0.2%, respectively. Several more recent studies describe complication rates of 15% to 28%.

Qualifying Statements

Qualifying Statements

- Clinical practice guidelines, practice advisories, systematic reviews, and other guidance published by the American Academy of Neurology (AAN) and its affiliates are assessments of current scientific and clinical information provided as an educational service. The information (1) should not be considered inclusive of all proper treatments, methods of care, or as a statement of the standard of care; (2) is not continually updated and may not reflect the most recent evidence (new evidence may emerge between the time information is developed and when it is published or read); (3) addresses only the question(s) specifically identified; (4) does not mandate any particular course of medical care; and (5) is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. The AAN provides this information on an "as is" basis and makes no warranty, expressed or implied, regarding the information. The AAN specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. The AAN assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.
- It should be recognized that the use of ventricular shunting for idiopathic normal pressure hydrocephalus (iNPH) is based largely on uncontrolled observational studies of clinical response.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Halperin JJ, Kurlan R, Schwalb JM, Cusimano MD, Gronseth G, Gloss D. Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2015 Dec 8;85(23):2063-71. [40 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Dec 8

Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

Source(s) of Funding

This guideline was developed with financial support from the American Academy of Neurology (AAN). Authors who serve as AAN subcommittee members or methodologists were reimbursed by the AAN for expenses related to travel to subcommittee meetings where drafts of manuscripts were reviewed.

Guideline Committee

Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology

Composition of Group That Authored the Guideline

Guideline Authors: John J. Halperin, MD; Roger Kurlan, MD; Jason M. Schwalb, MD; Michael D. Cusimano, MD, PhD, FRCSC; Gary Gronseth, MD; David Gloss, MD

Guideline Development, Dissemination, and Implementation Subcommittee Members: Cynthia Harden, MD (*Chair*); Steven R. Messé, MD (*Co-Vice-Chair*); Sonja Potrebic, MD, PhD (*Co-Vice-Chair*); Eric J. Ashman, MD, FAAN; Richard L. Barbano, MD, PhD, FAAN; Brian Callaghan, MD; Jane Chan, MD, FAAN; Diane Donley, MD; Richard M. Dubinsky, MD, MPH, FAAN; Terry Fife, MD, FAAN; Jeffrey Fletcher, MD; Michael Haboubi, MD; John J. Halperin, MD, FAAN; Yolanda Holler, MD; Andres M. Kanner, MD; Annette M. Langer-Gould, MD, PhD; Jason Lazarou, MD; Nicole Licking, DO; David Michelson, MD; Pushpa Narayanaswami, MBBS, DM, FAAN; Maryam Oskoui, MD; Richard Popwell, Jr., MD; Tamara Pringsheim, MD; Alejandro A. Rabinstein, MD, FAAN; Alexander Rae-Grant, MD; Anant Shenoy, MD; Kevin Sheth, MD, FAHA; Kelly Sullivan, PhD; Jonathan P. Hosey, MD, FAAN (*Ex-Officio*); Stephen Ashwal, MD, FAAN (*Ex-Officio*); Deborah Hirtz, MD, FAAN (*Ex-Officio*); Jacqueline French, MD, FAAN (*AAN Guideline Historian, Ex-Officio, Voting*)

Financial Disclosures/Conflicts of Interest

Conflict of Interest

The American Academy of Neurology (AAN) is committed to producing independent, critical, and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. The AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least 3 AAN committees, a network of neurologists, *Neurology* peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com . For complete information on this process, access the 2004 AAN process manual (see the "Availability of Companion Documents" field).

Disclosure

J. Halperin serves on the editorial boards of *The Neurologist* and *ACP Smart Medicine*; serves on the *Neurology* journal Level of Evidence Review Team; has received honoraria for continuing medical education lectures; has received research support from the Centers for Disease Control and Prevention; and has given expert testimony and acted as witness or consultant regarding the defense of several physicians in medical malpractice cases. R. Kurlan serves as a supplement editor for *Neurology*; serves on the editorial board of *Tremor and Other Hyperkinetic Movements*; serves on the speakers bureau of Teva Pharmaceuticals; receives research support from the National Institutes of Health (NIH), Kyowa, AstraZeneca, Rhythm, and Phytopharm; and served as a consultant on a medical malpractice case related to alleged missed diagnosis of normal pressure hydrocephalus (NPH). J. Schwalb serves on the Michigan Parkinson Foundation Physician and Epilepsy Foundation Physician Advisory Board; is a member of the American Association of Neurological Surgeons Subspecialty MOC Educational Materials and the *Congress Quarterly* editorial boards; has received honoraria from Medtronic; performs shunt placements for NPH; and has received research support from the NIH and internal grants from the Henry Ford Health System Neuroscience Institute. M. Cusimano reports no disclosures relevant to the manuscript. G. Gronseth serves as an evidence-based medicine methodologist for the AAN and serves on the *Neurology* Level of Evidence editorial board. D. Gloss serves as an evidence-based medicine methodologist for the AAN and serves on the *Neurology* Level of Evidence editorial board.

Go to Neurology.org for full disclosures.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

A list of American Academy of Neurology (AAN) guidelines, along with a link to this guideline, is available from the AAN Web site .

Availability of Companion Documents

The following are available:

- Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response. Data supplement (e-appendices, e-references, e-tables). St. Paul (MN): American Academy of Neurology; 2015. Available from the Neurology Journal Web site .
- Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response. Podcast. St. Paul (MN): American Academy of Neurology; 2015. Available from the Neurology Journal Web site .
- Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response. Slide presentation. St. Paul (MN): American Academy of Neurology; 2015. 52 p. Available from the American Academy of Neurology (AAN) Web site .
- Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response. Summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology; 2015. 2 p. Available from the AAN Web site .
- Practice guideline: idiopathic normal pressure hydrocephalus: response to shunting and predictors of response. Continuing medical education course. St. Paul (MN): American Academy of Neurology; 2015. Available from the Neurology Journal Web site .
- American Academy of Neurology (AAN). Clinical practice guideline process manual, 2011 Ed. St. Paul (MN): American Academy of Neurology. 2011. 57 p. Available from the AAN Web site .

Patient Resources

The following are available:

- Idiopathic normal pressure hydrocephalus. Summary of evidence-based guideline for patients and their families. St. Paul (MN): American Academy of Neurology; 2015. 2 p. Available from the American Academy of Neurology (AAN) Web site .
- Treating idiopathic normal pressure hydrocephalus: for patients. Video. St. Paul (MN): American Academy of Neurology; 2015 Dec. Available from the AAN Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on March 18, 2016. The information was not verified by the guideline developer.

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